K091153

Summary of Safety & Effectiveness
SYNCHRON® Systems
Enzymatic CO2 (CO2E) Reagent

1.0 **Submitted By:**

Marine Boyajian
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JUL 13 2009

2.0 **Date Submitted:**

April 16, 2009

3.0 **Device Name(s):**

3.1 **Proprietary Names**
SYNCHRON® Systems Enzymatic CO2 (CO2E) Reagent

3.2 **Classification Name**
Bicarbonate/carbon dioxide test system (21 CFR § 862.1160)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
SYNCHRON Systems Enzymatic CO2 (CO2E) Reagent	UniCel DxC 600/800 SYNCHRON Clinical Systems CO2 rate pH	Beckman Coulter, Inc	K042291

5.0 **Description:**

The SYNCHRON Enzymatic CO2 (CO2E) Reagent is intended for use in the quantitative determination of Carbon Dioxide concentration in human serum or plasma. The SYNCHRON Systems CO2E assay is an enzymatic method utilizing phosphoenolpyruvate carboxylase (PEPC) and a stabilized NADH analog in two coupled enzymatic reactions. In the first reaction, PEPC catalyzes the reaction between phosphoenolpyruvate and HCO_3^- to yield oxaloacetate and inorganic phosphate. In the second step, oxaloacetate is reduced by a stable NADH analog to malate in the presence of malate dehydrogenase (MDH). The resulting decrease in absorbance at 410 nm is spectrophotometrically measured and directly proportional to the CO2 concentration in the test sample via measurement of bicarbonate ions (HCO_3^-). The SYNCHRON DxC Systems utilize a two-level calibrator for the Carbon Dioxide assay.
The SYNCHRON Enzymatic CO2 (CO2E) Reagent is designed for optimal performance on the UniCel DxC SYNCHRON Clinical Systems (UniCel DxC 600/800 SYNCHRON and UniCel DxC 600i/660i/680i/860i/880i SYNCHRON Access Clinical Systems). The reagent kit contains two 300-test cartridges that are packaged separately from the associated calibrator.

6.0 **Intended Use:**

CO2E reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems AQUA CAL 1 and 3, is intended for the quantitative determination of Carbon Dioxide in human serum or plasma.

Clinical Significance:

Carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

7.0 **Comparison to Predicate(s):**

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

	Similarities	
SYNCHRON Systems Enzymatic CO2 (CO2E) Reagent	Intended Use	Same
	Sample Types	Same
	Analytical Sensitivity	Same
	Calibrator	Same
	Differences	
SYNCHRON Systems Enzymatic CO2 (CO2E) Reagent	Analytical range	CO2E Reagent: 5.0 – 45.0 mmol/L CO2 ISE Reagent: 5.0 – 50.0 mmol/L
	Sample volume	CO2E Reagent: 6 µl CO2 ISE Reagent: 40 µl
	Reaction Type (Methodology)	CO2E Reagent: enzymatic method CO2 ISE Reagent: pH rate change method
	Instrument Platforms	CO2E Reagent: UniCel DxC 600/800 Systems CO2 ISE Reagent: SYNCHRON LX and UniCel DxC 600/800 Systems
	Calibration Frequency	CO2E Reagent: every 72 hours CO2 ISE Reagent: every 24 hours

8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, linearity, and imprecision experiments.

Method Comparison Study Results

Candidate	Platform	Slope	Intercept	R	N	Predicate Method
SYNCHRON Systems Enzymatic CO2 (CO2E) Reagent	UniCel DxC	0.974	0.514	0.996	143	UniCel DxC 800 SYNCHRON Clinical System CO2 rate pH

SYNCHRON Systems Enzymatic CO2 (CO2E) Reagent Precision Study Results

Sample	Mean (mmol/L)	S.D. (mmol/L)	%C.V.	N
Within-Run Imprecision				
Level 1	11.50	0.39	3.4	80
Level 2	27.50	0.52	1.9	80
Total Imprecision				
Level 1	11.50	0.53	4.6	80
Level 2	27.50	0.68	2.5	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 06-30-2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Marine Boyajian / Beckman Coulter, Inc. / Chemistry Systems Business Center

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
04/17/2009

3. ADDRESS *(Number, Street, State, and ZIP Code)*
200 S. Kraemer Blvd.
M/S W-110
Brea, CA 92821
US

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) (714) 961 - 6536
(Fax) (714) 961 - 4234

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

SYNCHRON Systems Enzymatic CO2 (CO2E) Reagent

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. **Warning:** A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
(Name) Marine Boyajian
(Title) Senior Regulatory Affairs Specialist

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
200 S. Kraemer Blvd.
M/S W-110
Brea, CA 92821
US

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) (714) 961 - 6536
(Fax) (714) 961 - 4234

15. DATE OF CERTIFICATION
04/17/2009

PSC Graphics: (301) 443-1090 EF

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Beckman Coulter, Inc.
c/o Ms. Marine Boyajian
Senior Regulatory Affairs Specialist
200 South Kraemer Blvd., M/S W-110
Brea, CA 92822-8000

JUL 13 2009

Re: k091153
Trade name: Synchron® Systems Enzymatic CO2 (CO2E) Reagent
Regulation Number: 21 CFR 862.1160
Regulation Name: Bicarbonate/carbon dioxide Test System
Regulatory Class: Class II
Product Code: KHS
Dated: April 20, 2009
Received: April 22, 2009

Dear Ms. Boyajian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K091153

Device Name: SYNCHRON® Systems Enzymatic CO2 (CO2E) Reagent

Indication For Use:

CO2E reagent, when used in conjunction with UniCel® DxC 800 System and SYNCHRON® Systems AQUA CAL 1 and 3, is intended for the quantitative determination of Carbon Dioxide in human serum or plasma.

Clinical Significance
Carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance

Prescription Use __X__ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091153